QUALITY ASSURANCE MANUAL GUIDELINES

1. SCOPE

1.1 This guideline defines the overall requirements for documenting the quality assurance program of manufacturers holding a Notice Of Acceptance issued by the Miami-Dade County Building Code Compliance Office, Product Control Division.

1.2 DEFINITIONS

a) NOA:	Product approval Notice of Acceptance issued by the Miami-Dade County Building Code Compliance Office, Product Control Division.
b) Quality Assurance Manual:	Documentation that comprises the quality assurance program.
c) Quality Assurance Entity:	Quality assurance entity means an entity approved by the Florida Building Commission pursuant to subsection 9B-72.100(5),F.A.C., to provide oversight and determine that the product or system is being manufactured or assembled, per the submitted description, test results, or calculations to establish continual product performance.

1.3 REFERENCE DOCUMENTS:

a) Section 553.842 Florida Statutes

b) Section 8-40 of the Code of Miami-Dade County

c) Miami-Dade County Administrative Order 10-3

d) Chapter 9B-72 F.A.C.

e) ANSI / ISO / ASQ Q9001:2000 guide

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2.0 QUALITY MANUAL

2.1 A Quality Manual shall be provided by the applicant and contain a management statement on its policy, and objectives for, and commitment to, quality. Evidence shall be provided that approved products, methods, or systems of construction are being manufactured under a Quality Assurance Program.

2.2 Each manufacturing site shall have a Quality Manual. The Quality Manual shall clearly identify the manufacturer's name, street address, phone-numbers, email address and legal status and contact information for member of organization identified in 3.1.

3.0 PERSONNEL, RESPONSIBILITY AND AUTHORITY

3.1 The Quality Manual shall define and indicate a member of the organization, irrespective of other duties, that shall have responsibilities and authority that includes:

3.1.1 Ensuring that processes are established, implemented and maintained,

3.1.2 Reporting and resolving quality assurance issues related to third parties on matters related to the quality assurance program.

3.1.3 This person shall have direct access to top management.

3.1.4 There shall be a management statement assigning the person designated in Section 3.1.

3.1.5 Relevant job description of personnel assigned to the quality assurance program.

3.1.6 Policy statement on qualification and training of personnel.

4.0 DOCUMENTATION REQUIREMENTS

4.1 The Quality Assurance Program needs to provide means to ensure that the Quality Manual is reviewed at planned intervals not to exceed 12 months to ensure the continuing suitability, adequacy and effectiveness of the system.

4.1.2 The Quality Assurance Program shall also provide means to ensure that changes or revisions to the Quality Manual are controlled to ensure that only current documentation is used in processes directly affecting the quality system.

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5.0 IDENTIFICATION AND TRACEABILITY

5.1 The Quality Manual shall provide consideration to the quality control of approved products and it shall clearly identify them in accordance with the product approval NOA.

5.2 The Quality Manual shall control and record how the product is to be identified. The Quality Manual shall clearly identify how products comply with label requirements consistent with the information noted in the labeling section of the NOA.

5.3 The Quality Manual shall provide means for the finished product to be traced back to the production and quality control records at the manufacturing facility.

6.0 PRODUCT REALIZATION

6.1 The Quality Manual shall include a production flowchart or a description of production methods, describing the process by which the product is manufactured.

6.2 The Quality Manual shall contain products description, specifications, assembly drawings and manufacturing tolerances.

6.3 The Quality Manual shall ensure that product realization is conducted according to planned and developed processes needed to achieve conformity to product requirements.

6.4 The manufacturer shall determine as appropriate the need to establish processes, documents, required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.

6.5 Records needed to provide evidence that the realization processes and the product meet requirements shall be maintained per Section 12.4.

7.0 QUALITY AUDITS AND INSPECTIONS

7.1 The Quality Manual shall specify the frequency of the quality audits and inspections that are conducted by third-party agencies. The manufacturer shall use the records of audits and inspections to demonstrate its ability to correct and prevent quality issues.

7.2 All third-party audit or inspection reports are to be filed with the Product Control Division no later than ten (10) days after the actual date in which they were conducted.

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7.3 All corrective action responses when requested are to be addressed in writing to the Product Control Division. Corrective actions taken shall eliminate the cause of any nonconformity in order to prevent recurrence.

7.4 Field complaints involving Miami-Dade County approved products brought by a Building Official, a Product Control Inspector, a customer or a member of the general public shall be addressed and documented by the manufacturer. All complaints shall be investigated and submitted to the Product Control Division addressing the root cause of the problem and the corrective action.

8.0 CONTROL OF INCOMING MATERIALS

8.1 Purchasing records shall describe the materials to be purchased, including when appropriate any requirements from the product NOA, procedures, processes and equipment.

8.2 The manufacturer shall establish and implement the inspection criteria or other activities necessary for ensuring that the purchased materials meet specified purchasing requirements.

8.3 All records of inspections or tests that are conducted on incoming material, such as mill test reports, certificates of analysis or certificates of compliance, measurements, etc. shall be readily available for inspection. Incoming nonconforming materials shall be controlled according to Section 10.0.

9.0 PRESERVATION OF PRODUCT

9.1 The manufacturer shall provide means to ensure the conformity of the product and its constituent parts including identification, handling, packaging and protection.

10.0 CONTROL OF NONCONFORMING PRODUCT

10.1 The manufacturer shall provide means to ensure that product that does not conform to the product requirements is identified and controlled to prevent unintended use or delivery of a nonconforming product.

10.2 The control of nonconforming products shall be defined in the documentation system.

10.3 All nonconforming products shall be segregated from production until disposition of the product is made by a relevant authority.

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11.0 MONITORING AND MEASUREMENT OF PRODUCT

11.1 The quality manual shall provide for means to determine the monitoring and measurements to be undertaken, and the monitoring and measuring devises needed to provide evidence of product conformity to predetermined requirements.

11.2 Where necessary to ensure valid results and measurement, the manufacturer shall identify adequate measuring and test equipment. Equipment shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measuring standards. Where no such standard exist or the calibration is done by a computer software, the basis used for calibration or verification shall be recorded.

11.3 Records of the result of the calibration shall be maintained per section12.0.

12.0 CONTROL OF DOCUMENTS AND RECORDS

12.1 The Quality Manual shall ensure that all documents and records related to the quality assurance of the product are controlled. All documents shall be legible and readily identifiable.

12.2 Records shall be maintained to provide evidence of conformity to product requirements. Records shall remain retrievable and legible.

12.3 The manufacturer shall establish a documented procedure for the identification, storage, protection, retrieval, retention time and disposition of records.

12.4 All records pertaining to third-party audits and inspections shall be maintained for a minimum of three (3) years.

13.0 CONTROL OF DESIGN AND DEVELOPMENT CHANGES

13.1 Design and development changes for product that have been issued an NOA shall be identified and records shall be maintained. All changes shall be reviewed, verified and issued a revised NOA by the Miami-Dade County Building Code Compliance Product Control Division before implementation.

13.2 Records of the result of the review of changes and any necessary actions shall be maintained for a minimum of ten (10) years.